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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,762	06/07/2006	Albertha Walhout	07917-232US1 UMMC 03-137	1626
26161 7590 03/19/2009 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER JOLKE, MICHELE K				
ART UNIT		PAPER NUMBER		
1636				
NOTIFICATION DATE		DELIVERY MODE		
03/19/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

# Office Action Summary

**Application No.**

10/561,762

**Applicant(s)**

WALHOUT ET AL.

**Examiner**

MICHELE K. JOIKE

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE/US)  
Paper No(s)/Mail Date 12/1/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed December 1, 2008. Claims 1-17 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed June 30, 2008 that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 11, 12 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al in view of Fields et al and in further view of Sugawara et al.

Claim 8 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of Luo et al.

Claims 9 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of Chalfie et al.

Claim 14 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of Cost et al.

Claims 15 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of US 5,965,368.

Claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Walhout et al, Fields et al and Sugawara et al as applied to claims 1-7, 11, 12 and 13 above, and further in view of US 5,525,490.

***Response to Arguments Concerning Claim Rejections – 35 USC § 103 (a)***

Applicant's arguments filed December 1, 2008 have been fully considered but they are not persuasive.

The following grounds of traversal are presented:

Walhout et al. does not teach or suggest the detection of DNA-protein interactions using a bait element of at least 250 base pairs flanked by lambda recombination sites. The present specification (at page 3, lines 12-14) defines a "bait element" as "a sequence of DNA that associates with, e.g., is bound by, a transcription factor," typically all or part of a promoter sequence. Further, Walhout et al. does not

teach or suggest a cell with a bait element (or even an ORF) integrated into its genome. Lastly, Walhout et al. neither teaches nor suggests determining whether an activator domain fusion protein has bound to a bait element.

Fields et al. does not teach or suggest (i) a cell having integrated into its genome a bait-reporter construct with a single copy of a bait element flanked by lambda recombination sites or (ii) detecting the binding of an activator domain fusion protein to the bait element.

Sugawara et al. does not teach or suggest a bait element having at least 250 base pairs as presently claimed. Further, Sugawara et al. fails to disclose or suggest the use of lambda recombination sites.

Luo et al., Chalfie et al and Cost et al do not teach or suggest the detection of DNA-protein interactions, a cell with a bait-reporter construct integrated into its genome, or a bait element flanked by lambda recombination sites.

The '368 and '490 patents do not teach or suggest a cell whose genome includes one or more integrated bait-reporter constructs, wherein each of the one or more bait-reporter constructs includes (a) a single copy of a bait element having at least 250 base pairs flanked by lambda recombination sites, wherein the bait element comprises at least 250 base pairs and (b) a reporter gene.

Applicant's arguments have not been found persuasive for the following reasons.

Walhout et al teaches a vector with an ORF of at least 250 bp and flanked by lambda recombination sites transformed into a yeast cell. The vector can be integrated into the genome (p. 579). Fields et al teach using a UAS/Gal4 system in a yeast two-hybrid assay. Therefore, Fields et al teach use of a bait element as defined by the specification. Fields et al also teach assessing activation of the reporter when the fusion protein of a DBD and TAD bind to the binding element (UAS<sub>G</sub>). See figure 1. It would be obvious to substitute the ORF taught by Walhout et al with the bait element taught by Fields et al, because Walhout et al teach the use of a vector with a binding domain, and Fields et al use UAS<sub>G</sub>, which is a binding domain. As for Sugawara et al, Chalfie et al, Luo et al and Cost et al, Walhout et al and Fields et al combined teach a bait element having at least 250 base pairs, the detection of DNA-protein interactions, a cell with a bait-reporter construct integrated into its genome, or a bait element flanked by lambda recombination sites. The same argument applies to patents '398 and '490. The other references cited are used to teach one or more bait-reporter constructs includes (a) a single copy of a bait element having at least 250 base pairs flanked by lambda recombination sites, wherein the bait element comprises at least 250 base pairs and (b) a reporter gene.

***Allowable Subject Matter***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **MICHELE K. JOIKE** whose telephone number is (571)272-5915. The examiner can normally be reached on **M-F, 10:00-6:30**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

Michele K Joike  
Examiner  
Art Unit 1636